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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,490	01/07/2002	Gavriel Meron	P-2038-US1	4535

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EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,490

Applicant(s)

MERON ET AL.

Examiner

Gary W. Counts

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-11,14-16,18-44,46-48 and 50 is/are pending in the application.
4a) Of the above claim(s) 23-44,47 and 48 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 3-5, 7-11, 14-16, 18-22, 46 and 50 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |



DETAILED ACTION

Status of the claims

The Request for Continued Examination and the Amendment filed August 9, 2005 is acknowledged and has been entered. Claims 1, 3-5, 7-11, 14-16, 18-44, 46-48 and 50 are pending. Claims 23-44, 47 and 48 are withdrawn from consideration as being directed toward a non-elected invention.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1, 3, 8, 14, 15, 18-22, 46 and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Colvin Jr. et al. (US 6,330,464).

Colvin, Jr. et al disclose a capsule (Figure 1) comprising a matrix (solid support) having immobilized thereon a fluorescent indicator molecule (reactant) which interacts

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with an analyte (substance) (col 15) to cause an optical change. Colvin Jr, et al disclose that the capsule comprises a detector (Fig 1. item 20)(detecting unit). Colvin Jr, et al. discloses that the capsule comprises a power source and that the power source can be a battery (col 10, lines 53-59). Colvin Jr, et al disclose the capsule comprises a radiation source (illuminating element). Colvin Jr, et al disclose that the capsule can comprise a transmitting unit (col 10).

With respect to the "autonomous swallowable capsule" as recited in the instant claims. An autonomous swallowable capsule is intended use of the system and the Colvin Jr. capsule is capable of being swallowed and passed through the digestive system and thus is capable of being an autonomous swallowable capsule.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 3-4, 7, 8, 14-16, 18-22, 46 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs et al in view of Alfano et al (US 6,240,312).

Kovacs et al discloses an implantable biosensing transponder comprising a biosensor which may sense optical, mechanical, or chemical properties. The device also includes a transponder for wirelessly transmitting data corresponding to the sensed parameter to a remote reader. Disclosed embodiments use chemical sensors and pressure sensors (abstract). Nearly any type sensor can be used with the transponder of the reference, and the transponder can be used to measure a variety of parameters, including blood chemistry, such as sugar and hemoglobin levels (col. 3). The biosensor may be completely positioned within a capsule (Col. 4). In one embodiment, the transponder includes photosensors for optically detecting physical properties at the implant site. The biosensor may comprise an array of photosensors, such as an imager, for providing an image of the implant site. Biosensing transponders using photosensors can also include one or more optical emitters for illuminating the implant

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site with specific wavelengths of light. For example, chemical sensitive dyes may be illuminated to detect a change in an optical property of the dye to detect a physical property of the external environment. The capsule may be implanted in contact with tissue or blood. Another dye of the same type of dye as is located on the exterior of the capsule is located within the capsule. The capsule is constructed from transparent glass. An optical emitter illuminates the dyes and causes them to emit fluorescence, and photosensors detect the optical properties of the dyes upon illumination. Dye on the outside of the capsule interacts with the environment to produce an optical change, which can be compared to dye within the capsule (Col. 10). Photosensors can also be used for direct optical sensing of the environment, such as for determining color of an organ (Col. 11).

Kovacs et al fail to teach a battery within the capsule.

Alfano et al teach sensors for in vivo use. Alfano et al disclose that the sensor which can be swallowed (col 4) can comprise a battery. Alfano et al disclose that the battery provides a source of power necessary for the internal computer operation and controllers of the device (col 5, lines 25-47) and provides for a wireless, remote-controllable micro-scale device that is used within a patient. (col 1- col 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a battery as taught by Alfano et al into the device of Kovacs et al because Kovacs et al teaches that it is known in the art to use a battery in small devices (col 2, lines 46-54) and further because Alfano et al teaches that the battery provides a source of power necessary for the internal computer operation and

controllers of the device and provides for a wireless, remote-controllable micro-scale device that is used within a patient. Thus one of ordinary skill in the art would have a reasonable expectation of success incorporating a battery as taught by Alfano et al into the device of Kovacs et al.

7. Claims 5 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kovacs et al. and Alfano et al in view of Atarashi et al. (US 6,162,469)..

See above for the teaching of Kovacs et al and Alfano et al.

Kovacs et al and Alfano et al. differ from the instant invention in failing to teach a biological reactant and a plastic support.

Atarashi et al. teach a medical powder which comprises polymeric microspheres having thereon immobilized antigen or antibody for detection or diagnosis purposes. The powder may be used in vivo.

It would have been obvious to one of ordinary skill in the art the time the invention was made to use a biological compound as the reactant as in Atarshi et al. on the support of Kovacs et al. because Atarashi et al. teach that biological compounds bound to supports may be used in vivo further, depending on the analyte of interest, one of skill in the art could have used its appropriate receptor with a reasonable expectation of success that it would function in a manner similar to the dye of Kovacs et al. In addition, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. It would have also been obvious to use plastic as the support material with the device of Kovacs and Alfano because any

transparent material would have worked with the optical sensor of Kovacs. In addition, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

8. Applicant's arguments with respect to claims 1, 3-5, 7-11, 14-16, 18-22, 46 and 50 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

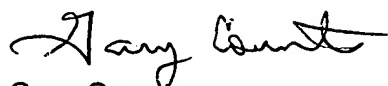
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Gary Counts
Examiner
Art Unit 1641
September 13, 2005



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SUPERVISORY PATENT EXAMINER
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09/13/05